May 11, 2021

Dr. Tala Henry, Deputy Director for Programs
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460–0001

RE: Confidential Business Information (CBI) Status Changes and the 2020 Chemical Data Reporting Rule

Dear Tala:

The American Chemistry Council (ACC) appreciates that EPA provided companies claiming some 390 chemical identities confidential on the 2012, 2016, and/or the 2020 TSCA Chemical Data Reporting (CDR) rules a brief window (until May 14) in which to contact the agency to report potential errors in EPA's evaluation of their CBI claims.[1] However, EPA has not provided sufficient time—a mere 10 business days—for companies to review and evaluate whether they believe EPA has committed errors when identifying the 390 substances as potentially subject to disclosure in late summer 2021. Given the significant competitive commercial value confidential chemical identities have to U.S. chemical companies, EPA should extend the time within which companies may notify EPA of any potential errors through at least June 30, 2021.

EPA staff has stated in a private conversation that the 390 confidential chemical identities identified on April 30, 2021, bear no relationship to the approximately 2800 confidential chemical identities that EPA identified as likely to be disclosed as a result of the TSCA Inventory Reset process. However, ACC has conducted an analysis of the two lists and identified a striking number of overlapping substances—approximately 345. This overlap is very concerning as it suggests that EPA may very likely be making the same erroneous assumptions made when evaluating the 2800 confidential chemical identities following the Inventory Reset, i.e., that processors or other actors in the supply chain who do not possess the requisite knowledge of the actual chemical identity of a confidential chemical may waive a confidential chemical identity's CBI status by failing to provide a substantiation of the chemical. This is a wholly improper reading of TSCA and the U.S. laws regarding CBI. ACC has detailed its concerns in September and October 2020 letters to former Assistant Administrator Dunn, both of which are attached to this letter as Appendix A and continue to await EPA's correction of this flawed analysis.

[1] See EPA's April 30, 2021, announcement regarding 390 confidential chemical identities on the 2012, 2016, and/or 2020 CDR at Updates to Confidential Status of Chemicals on the TSCA Inventory | Confidential Business Information under TSCA | US EPA

EPA should take clear, demonstrable, and transparent steps to ensure each company associated with the 390 confidential chemical identity claims are ***not*** denied CBI protection based on the same or a similar erroneous analysis as was revealed with the Inventory Reset as outlined above. Just as EPA's CBI regulations require any person seeking to maintain a claim for confidential chemical identity in the first instance to submit to EPA the **specific identity of the chemical**, logic requires that it must also be a prerequisite to waiving a CBI claim for that confidential chemical identity.[2]

Therefore, ACC believes EPA must provide companies claiming any one or more of the 390 confidential chemical identities listed for potential disclosure in late summer 2021, written denials of those claims, which also clearly outline the basis for the denial and assurance that EPA has not relied upon a supposed waiver by an entity in the supply chain that has not demonstrated to EPA that it possesses knowledge of the actual chemical identity of the confidential chemical identity.

Further, ACC is concerned that EPA is relying on information submitted during the 2020 CDR as a basis upon which to deny certain confidential chemical identities on the 390 substances list when the 2020 CDR was plagued with disruptions, errors, and other systemic failures of the Central Data Exchange (CDX) reporting system. CBI is critically important to industry's competitive interests and should not be put at risk of disclosure due to the poor functionality of EPA's CDX system exhibited during the 2020 CDR reporting cycle. EPA must take significant steps to verify that a valid claim and substantiation were not attempted by the CDR submitter and lost due to CDX functionality failures.

The significant problems associated with the CBI substantiation portion of the 2020 CDR CDX reporting system were originally documented in ACC's Request for Extension[3] (RFE) and continued throughout the entire reporting cycle, which ended on January 29, 2021. The technical issues with the CDX reporting tool included an all-out system crash, system-preview defects, CBI substantiation system malfunctions, validation errors, and co-manufacture reporting glitches. Although EPA and its contractor worked consistently to remedy these issues throughout the reporting period, significant problems persisted even after the reporting deadline expired. In addition to the recurring problems, new issues arose each time a corrective patch was deployed, resulting in additional problems, delays, and concerns that data and information entered may be corrupted and rendered unreliable.

Identified below are some of the more egregious examples of CDX problems specifically impacting CBI data elements in the 2020 CDR:

CBI Substantiation Issues:

- A September 2020 CDX corrective patch crashed the system and caused the entire CBI substantiation section, CBI headers, or specific substantiation questions to disappear or reproduce content multiple times.
- In many situations, submissions uploading more than 100 chemicals did not generate the green checkmark showing that all substantiations were complete for a given chemical. The submitter

[2] 40 CFR 720.85
[3] Request for Extension dated October 26, 2020, attached as Appendix B.

was forced to validate the entire form to discover any missing substantiations in substances > 100. The green checkmark would appear only for the first hundred chemicals entered. This system failure to generate the appropriate validation confirmations left submitters uncertain their information was recorded and/or received accurately. These issues persisted until the close of the 2020 reporting cycle.

- The substantiation copy and paste functionality failed to operate correctly once a submitter sought to apply it to more than 200 substances at one time, forcing companies to copy and paste a substantiation manually to each applicable substance. For companies with significant numbers of chemicals, this tedious and time-consuming process was laborious and increased the overall CDR burden.

- On Co-Manufacturing Submissions, the Form U consistently prompted the Contracting Company, who may not have the requisite knowledge of actual chemical identity or the facts necessary to substantiate a confidential chemical identity claim, to substantiate the CBI claim, stalling and delaying further an already laborious co-manufacturing submission process.[4]

The CDX problems associated with CBI substantiations prevented submitters from confirming the content and accuracy of their submissions, which in turn, has created significant uncertainties about whether inadvertent disclosures of CBI will occur as a result.

Preview generation and viewing issues: ACC's October RFE noted multiple issues with preview generation, e.g., companies unable to view and/or preview their draft submissions prior to final submission to EPA. These problems continued throughout the reporting cycle. Member companies implemented elaborate and time-consuming workarounds in attempts to circumvent this issue. The preview and review process is a critical step for companies during the reporting process. Without the ability to view their complete Form U prior to submission, companies cannot ensure the reliability of the submitted data or have confidence that their CBI substantiations are reflected accurately.

Co-Manufacturing Submissions: As a result of the changes to the co-manufacturing reporting procedure in the 2020 CDR Rule, contracting companies were no longer able to complete the Form U independently. ACC members experienced significant issues with the email contact system in CDX and were forced to wait weeks for this key feature to become operational so that they could begin the data-entry process. As companies worked through the process, they noticed that inaccurate information was transmitted to their co-manufacturer and/or the co-manufacturer was required to respond to questions that the Contracting Company was unable to answer. Due to these system issues, many companies were required to spend significant time ensuring that they and their co-manufacturers were able to

[4] This appears to be an example where EPA erroneously believes that businesses routinely share CBI with one another when they are contractually or otherwise conducting business together, e.g., subject to a non-disclosure agreement. While it is certainly possible that some businesses may do this, it is by no means typical or commonplace, and it is certainly not legally required. This erroneous assumption by EPA may lead to the agency's improper disclosure of confidential chemical identities. EPA should not program its CDX to presume companies operate in this fashion. The only entity in a business transaction that is contemplated by a Co-Manufacturing Submission that is capable of providing a substantiation is the entity possessing actual knowledge of a confidential chemical identity; not the entity with mere knowledge that a confidential chemical identity has an accession number associated with it. Please see ACC correspondence to EPA regarding this issue arising in the context of EPA's Inventory Reset rule, attached as Appendix A.

complete the submissions as the system did not necessarily prompt the correct party to answer a substantiation question.

Submission processing issues: As members began submitting Form U's, an issue arose that stalled the submission in the processing phase. This issue was identified inadvertently when company representatives tried to make a correction on a form submitted weeks earlier and discovered the form stuck in the "processing" stage. To remove the Form from the processing stage, one had to contact EPA or its CDX contractor to have the form "unlocked" and reviewed for errors. No validation errors were ever triggered when this occurred, and no notification was ever sent to the submitter. ACC member companies were advised to follow-up with all submissions to confirm that their submissions had been fully confirmed by EPA. This issue was never resolved, and several ACC members continued to correct errors due to technical malfunctions in the CDX system for extended lengths of time—in some cases continuing even after the reporting period closed.

General form completion issues:

- Partial Exemptions for Chemicals fields required data entry – As a result of one patch update, the partial exemption for chemicals (40 CFR 711.6(b)(2)(iv) was deleted and data was required in that field in order to proceed with validation. Although it was reported that this issue was resolved, the issues continued to recur following the near-weekly CDX system updates that continued through to the end of the reporting period. As a result of this longstanding issue, member companies were told by EPA's contractor to enter "NRKA" if they did not want to wait for the corrective patch. The reporting of "NRKA" presents additional issues that CDR submitters should not have had to face when a partial exemption is available.[5]

- Miscellaneous Validation Errors – Validation errors were not triggered when information was missing, incomplete, or entered improperly. Many submissions that did not trigger validation errors were submissions caught in the processing stage. In several instances, a city or state entry was missing or incorrectly entered, or hidden characters, blank spaces, and special characters caused a "freeze." Within the CBI substantiation section, once a site reported more than 100 chemicals, the system would not permit individuals to validate responses. With each of these validation errors, ACC members were required to contact the CDX HelpDesk or EPA for assistance or troubleshooting.

* * * * *

As a result of the CDX technical issues outlined in this letter and ACC's October Request for Extension, we strongly urge EPA to work closely with any CBI submitter to ascertain whether a CBI substantiation may have been provided by a CDR reporter but one or more CDX system failures interfered with the successful transmission of a claim and/or substantiation. Companies should not be penalized for CDX system errors outside and beyond their control.

In addition, ACC requests that EPA 1) extend the period to June 30, 2021, for companies to notify EPA of potential errors in listing any of the 390 confidential chemical identities as potentially subject to

[5] Consequently, some companies had to certify their CDR submissions containing NRKA, as instructed by EPA's contractor, where partial exemption fields were not functional, thereby compromising accuracy of the information contained in the 2020 CDR.

disclosure, and 2) provide written notice to any company as required under TSCA section 14(g) of its basis for denying a confidential chemical identity claim, and confirmation that EPA has not relied upon a purported waiver of a CBI claim from some other actor in the supply chain that does not possess the actual identity of the confidential chemical that is the subject to disclosure.

Please let me know if you have any questions.

Sincerely,

Christina Franz

Christina Franz
Senior Director
Regulatory & Technical Affairs

cc: Michal Freedhoff, Acting Assistant Administrator
Yvette T. Collazo, Director OPPT
Pamela Myrick, Director, Project Management and Operations
Scott Sherlock
Susan Sharkey

American Chemistry Council

Attachment A

September 15, 2020

Assistant Administrator Alexandra Dunn
Mail Code: 7101M
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Alex:

I want to bring to your attention a significant issue regarding EPA's implementation of the amended TSCA Inventory Reset rule that is adversely impacting certain claims for confidential chemical identity. We believe this issue, affecting a number of ACC member companies, requires your intervention to ensure that confidential chemical identities are not inadvertently or improperly disclosed.[1]

During the Inventory Reset process, manufacturers, importers, and processors (submitters) identified chemical substances that were active in commerce according to specific criteria. Submitters were permitted under the Inventory Reset rule to identify confidential chemical identities for the TSCA-Active Inventory, using the designated Accession Number, despite not having been the original claimant of the CBI claim.[2] In some cases, importers or processors may have an Accession Number, but this is not the same as knowing the chemical identity of that substance.

Submitters identifying a confidential chemical identity were prompted to complete *Part III – Status of Confidential Chemical Substance Identity,* which included two optional statements: 1) "I am seeking to maintain an existing claim of confidentiality for the specific chemical identity, as listed on the TSCA Inventory," or 2) "I am not seeking to maintain an existing claim of confidentiality for the specific chemical identity, as listed on the TSCA Inventory." The second option should have, but did not inquire further of the submitter to clarify the relationship to the confidential chemical identity, i.e., clarifying whether the submitter was the owner of the CBI claim, knew the true identity of the chemical, and was in a position to actually provide a substantiation or waiver of the CBI claim.[3]

[1] For example, see enclosed August 18, 2020, letter to Yvette Colazzo-Reyes from Dupont.
[2] This, in part, was motivated by congressional intent to ensure that manufacturers, importers, and processors all had an opportunity to prevent a confidential chemical active in commerce from being inadvertently misreported as inactive.
[3] Some companies report that in instances where they were not the CBI owner, they voluntarily communicated on the Form A that they were not the CBI owner, but this was not a requirement of EPA's Inventory Reset rule.

Despite the fact that Form A did not establish every submitter's bona fide right to assert and substantiate a confidential chemical identity claim, the agency is relying improperly on submissions that selected option 2, "I am not seeking to maintain an existing claim of confidentiality for the specific chemical identity, as listed on the TSCA Inventory," to override a bona fide owner's CBI claim and substantiation. A legitimate CBI claim requires actual knowledge of the very thing for which protection from disclosure is sought—in this instance, the true chemical identity.

It appears that EPA is either concluding that a submitter selecting option 2 possesses that requisite knowledge of the actual chemical identity without sufficient evidence or that simply possessing the Accession Number as an importer/processor during the ten-year lookback period is sufficient to enable it to invalidate a confidential chemical identity claim. Neither of these conclusions is appropriate based on the superficial information requested by EPA in the Inventory Reset.

If EPA is taking steps to ascertain the specific knowledge and rights of each submitter to assert/waive a valid claim for CBI protection, the agency should make those steps known to the other submitters who answered in the affirmative to option 1): "I am seeking to maintain an existing claim of confidentiality for the specific chemical identity, as listed on the TSCA Inventory." Ideally, EPA will publicly and transparently demonstrate that it has taken sufficient steps to uphold legitimate claims to protect confidential chemical identities.

We urge you to take steps immediately to prevent the agency from disclosing confidential chemical identities without first establishing that any purported waiver of a confidential chemical identity claim has been made by an entity possessing the legal authority to do so.

Please let me know if you have any questions.

Sincerely,

Christina Franz

Christina Franz
Senior Director, Regulatory & Technical Affairs

cc: Yvette Collazo-Reyes
Pamela Myrick
Scott Sherlock

Yvette Collazo-Reyes
US EPA Headquarters
William Jefferson Clinton Building
1200 Pennsylvania Avenue, NW
Mail Code: 7401M
Washington, DC 20460

Dear Ms. Collazo-Reyes,

DuPont is writing in support of the letter submitted by [redacted] on August 17, 2020 and their intent to amend the Form A relevant to Accession Number 173741 such that the specific chemical identity claim is asserted and substantiated. Upon amending this Form A, this substance should not be removed from the Confidential side of the TSCA-Active Inventory nor should the identity be made public. Disclosure of the claimed CBI would result in harmful effects on DuPont's competitive position since the Company has committed a significant amount of time, resources, and dollars to the research and development of these substances. Allowing competitors to access the identities of the proprietary substances will allow them access to DuPont's technology without the associated development costs. This inability to fully recoup development costs ultimately disincentives further investments in new technologies within US markets.

Key Points

1. **The language in Part III of the Form A does not state that CBI should be rescinded.**

   During the TSCA Inventory-Reset period when Manufacturers, Importers, and Processors submitted chemical substances for the TSCA-Active Inventory, the chemicals with an Accession Number prompted the submitter to fill out *Part III – Status of Confidential Chemical Substance Identity.* There were two options 1) "I am seeking to maintain as existing claim of confidentiality for the specific chemical identity, as listed on the TSCA Inventory," or 2) "I am not seeking to maintain as existing claim of confidentiality for the specific chemical identity, as listed on the TSCA Inventory." That language does not ask if the submitter knows the confidential chemical's true chemical identity. Nor does it ask if the submitting company has standing to substantiate or not substantiate the CBI claim.

   [redacted] is a longtime customer of DuPont. In this capacity, DuPont was able to speak with them about their Form A submission during 2018 and they stated that their intent was not for specific chemical identity to be revealed. Neither DuPont as the manufacturer, nor [redacted] as the customer, want the substance moved to the public side of the TSCA-active inventory. This would present scenarios for both companies with substantive harm to their competitive position.

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2. **The Substance is not in the public domain.**

   The specific chemical identity (name and/or CAS number) of the substance associated with Accession number 173741 is not currently in the public domain. The specific chemical identity is not disclosed on SDSs or public literature. To the best of our knowledge, the specific chemical identity has never been disclosed to our customer [redacted] under a non-disclosure agreement nor provided outside of one. Since the PMN for Accession number 173741 dates to 1997, there would have been ample time for the Accession Number to be shared with the customer and indeed the EPA has always encouraged manufacturers to share Accession Numbers such that customers could independently verify TSCA status.

   DuPont maintains information relevant to the substance's specific chemical identity on documents marked as CONFIDENTIAL or CONFIDENTIAL BUSINESS INFORMATION. Disclosure of the subject material's identities within the Company is on a need-to-know basis on secure servers. Employees who do have access to the information are contractually prohibited from unauthorized disclosure of such information. Any outside sampling that may have occurred was done under non-disclosure confidentiality (secrecy) agreements.

3. **DuPont and [redacted] have acted in a timely manner to resolve this CBI issue**

   Neither DuPont nor [redacted] (to the best of our knowledge) have received notification of CBI claims being denied. DuPont learned of the list of substances potentially losing CBI protections via the 2020 CDR submission process. Upon verification of Accession number 173741 on this list, DuPont took action as quickly as possible speaking internally with the relevant business representatives, externally with the ACC (Christina Franz), with the EPA (Scott Sherlock), and then with [redacted] and their external TSCA consultant.

In compliance with the Inventory Reset (Active-Inactive Rule) DuPont submitted Form A's for substances with Accession Numbers 173741[1] in a timely manner and provided chemical identity CBI Substantiation at the time of submittal. The Company's CBI claims were not rejected. Our understanding is that [redacted] as a customer and re-importer of Accession Numbers 173741 also submitted a Form A in a timely manner.

The Agency has not proven that the chemical identity of the substance with Accession Number 173741 does not meet all requirements for protection as CBI under TSCA Section 14. Thus, revoking the CBI's protected status and publicly disclosing the substance's full chemical identity would be in violation of

[1] Submitted via CDX on 2018-2-7 by E.I. DuPont de Nemours; CDX receipt 2d33663f-3560-4583-b8a1-11644adb70ed

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the protections allowed under this section. Disclosure of the claimed CBI would result in harmful effects on DuPont's competitive position since the Company has committed a significant amount of time, resources, and dollars to the research and development of this substance.

DuPont strongly opposes the potential move of this substance to the public TSCA-Active Inventory, and we strongly support [redacted] ability to amend the Form A, allowing them to assert and substantiate the CBI claim.

Sincerely,

[redacted]

October 29, 2020

Assistant Administrator Alexandra Dunn
Mail Code: 7101M
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Alex:

Thank you for meeting with us last week to discuss the current implementation issues adversely impacting certain confidential chemical identity claims made under the Inventory Reset rule. As we noted, we believe that oversights in the rule were not apparent until it was implemented.[1] We wanted to summarize here the key points we raised on this issue during our meeting.

Confidential chemical identities are among the most valuable forms of intellectual property chemical companies possess. EPA's current policy regarding its review of confidential chemical identity claims under the Inventory Reset rule is threatening to disclose valid claims based on mistaken assumptions regarding **who** is legitimately authorized to substantiate a confidential chemical identity claim and, conversely, who has the ability to nullify a confidential identity claim.

Confidential chemical identities are listed on the Inventory Reset by their Accession Number and generic name only. The Accession Numbers and generic names are publicly available. Every chemical with an Accession Number and generic name is, by definition, known to be a confidential chemical identity. Anyone completing a Form A, identifying a confidential chemical identity, was required to check one of two statements:

- **Option 1**: "I am seeking to maintain an existing claim of confidentiality for the specific chemical identity, as listed on the TSCA Inventory," or
- **Option 2:** "I am not seeking to maintain an existing claim of confidentiality for the specific chemical identity, as listed on the TSCA Inventory."

Active chemicals (confidential and non-confidential) could be identified by anyone who was a manufacturer, importer, or processor, regardless of their commercial relationship to the chemical. EPA did not require Form A submitters to assert or establish that they possess the requisite knowledge of the specific chemical identity if they selected Option 2. The Agency is, however, treating Option 2 responses as a knowing waiver of an existing confidential chemical identity claim. In effect, a confidential chemical identity claim substantiated by an entity with actual knowledge of the specific identity can be overridden by another entity's selection of Option 2, however inadvertent and without actual knowledge of the specific chemical identity. As we noted, Option 2 neither confirms knowledge of specific identity nor specifies a waiver of confidential status.

[1] See https://www.epa.gov/tsca-fees/information-plan-reduce-tsca-fees-burden-and-no-action-assurance

We believe that, more often than not, a company without knowledge of the specific identity that identified a confidential chemical identity as Active and selected Option 2 (not maintaining a claim) did so without malicious intent to undermine a valid CBI claim. It is likely that the company assumed the manufacturer or importer with knowledge of the specific identity would satisfy the substantiation requirements due on November 1.

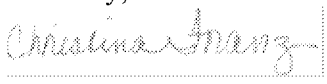
Discussions with EPA staff revealed that EPA assumes that the chemical industry routinely enters into non-disclosure agreements with its customers regarding confidential chemical identities that are the subject of commercial transactions. This is not the case. While it is possible that some businesses may have a non-disclosure agreement with customers, it is not customary practice. One of the key methods a company uses to protect its confidential information is to employ the Accession Number and generic name in lieu of the CAS# and specific chemical name.

ACC member companies are concerned that EPA's approach under the Inventory Reset rule signifies that EPA will **not** protect CBI claims for confidential chemical identity. Such a result would be inconsistent with clear congressional intent that CBI be protected under TSCA as it was amended in 2016.

We ask that EPA establish a clear policy that the agency will not disclose a confidential chemical identity on the basis of an entity's statements or lack of substantiation without first ascertaining that the submitter possesses the requisite knowledge of specific chemical identity and is not subject to a non-disclosure agreement or other similar restriction before the agency will deem a confidential chemical identity claim has been waived.[2] This policy should be applied consistently across TSCA.

Please let me know if you have any questions.

Sincerely,



Christina Franz
Senior Director, Regulatory & Technical Affairs

cc: Yvette Collazo-Reyes
Tala Henry
Lynn Dekleva

[2] We note that EPA's CBI regulations at 40 CFR 720.85 requires any person who seeks to maintain a claim for confidential chemical identity in the first instance must submit to EPA a generic name and the specific identity of the chemical. Knowledge of the specific identity is thus a prerequisite to seeking approval of a claim under EPA's regulations. Similarly, it should also be a prerequisite to waiving a CBI claim for that confidential chemical identity.

American Chemistry Council

MICHAEL P. WALLS
VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

Attachment B

October 26, 2020

Ms. Susan Sharkey
Chemical Control Division
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460–0001

RE: Request for an Extension to the TSCA Chemical Data Reporting (CDR) 2020 Submission Period

Dear Ms. Sharkey:

The American Chemistry Council (ACC) requests an extension of 60 days to the 2020 submission period for the Chemical Data Reporting (CDR) Rule (76 Fed. Reg. 50816, April 9, 2020) from the current November 30, 2020, deadline to January 31, 2021. In light of the significant problems regulated entities have had accessing and using the Chemical Data Exchange (CDX) system to make their CDR submissions, and because no significant decision of the Environmental Protection Agency (EPA) relies on the CDR data in the short term, we believe a 60-day extension of the reporting deadline is warranted. Should EPA grant a shorter extension, we believe EPA should re-evaluate the need for a longer extension by mid-December, 2020, depending on how quickly (or not) the problems noted below are resolved.

ACC and its member recognize the need for accurate information submitted to the CDX and note that extending the deadline will not affect the processing and release by EPA of this data.

The 2020 CDR submission period began June 1, 2020. Since the reporting began, ACC members have reported a wide variety of technical issues that have significantly impeded their ability to upload, validate, and submit electronic data submissions. These problems have generally not been resolved.

Chief among the submitters' concerns are: an all-out system crash, system preview glitches, CBI substantiation system malfunctions and validation errors. We recognize that EPA and its contractor, CGI, have consistently worked to remedy these issues throughout the reporting period, but many key issues remain unresolved. In addition to recurring problems, new issues are arising, rendering the CDR reporting system an obstacle to efficient reporting of data and information within the timeframe allotted.

The following problems have negatively impacted the submission of CDR data via the CDX:

CDX system crashes: On or about September 29, 2020, the entire CDX system crashed for approximately two weeks. This crash caused the following issues for CDR reporters:

- inability to access CDR forms;
- validation errors, including new and recurring validation errors where none existed previously;
- inability to create a submission preview and/or prevented the viewing of a preview if one could be generated;
- no confirmation emails for submissions completed.

This system-wide crash forced reporters to halt their submissions. Although the CDX system is operational, it remains extremely slow and unreliable. Overall, the issues remains unresolved.

Confidential Business Information (CBI) substantiation issues: The bulk upload approach prevented the upload of CBI substantiation data. ACC members attempted to "copy and paste" their substantiation from Word documents into their Form U as suggested by EPA, but this produced hundreds of pages of corrupted symbols and special characters in the preview section of CBI substantiations. The "correction" deployed to remedy the "copy and paste" issue created at least two new corruption issues within the Form U and the crash of the CDX system. One of those new problems in the Form U was that either the full CBI substantiation section and/or the header disappeared or some CBI substantiations appeared multiple times. This new issue remains unresolved.

In addition, the "copy and paste" function within the Form U only permits a one-time use. Once that function is utilized, the function disappears. Any corrections necessary once the "copy and paste" function disappears must be completed manually to each chemical. For some companies having a large number of CBI claims (e.g., 50-150), this is a significant burden. This issue remains unresolved.

On Joint Submissions, the Form U consistently prompts the primary submitter, who may not have the requisite knowledge of actual chemical identity and facts, to substantiate the CBI claim, further stalling the already slow co-manufacturing submission process.

The problems associated with substantiations create significant uncertainties about inadvertent disclosures of confidential information caused by the CDX, and have prevented submitters from confirming the validity of their submissions.

Preview generation and viewing issues: Member companies reported multiple issues with preview generation for several months to the CDR HelpDesk. This issue has never been fully resolved and only a very tedious and time consuming "work-around" has been offered by EPA and its contractor. The preview and review process is a critical step for companies during the reporting process. Without the ability to view their complete Form U prior to submission, companies cannot ensure the reliability of the submitted data or have confidence that their CBI substantiations are reflected accurately. This issue remains unresolved.

Bulk upload: Data input and upload issues have arisen as a result of updates to the system, resulting in delays and additional system issues. In these circumstances, templates either: fail to upload all information; improperly align the data upload within the form; the bulk uploads

result in duplications; or the information uploaded cannot be saved. Issues related to the XML template remain unresolved.

Authorized Official/Facility/Sites/Parent Company inaccuracies: ACC members have experienced significant difficulties creating accounts and linking them to appropriate facility sites and authorized users. Although this issue was reported to EPA in each of the last several reporting cycles, the "Manage Facilities" section is replete with multiple listings for the same site. These listing have misspellings for business entity names, incorrect and/or misspelled addresses, and duplicative listings resulting in significant difficulty for companies to confirm which entry identified was the correct one. Companies have been forced, in some circumstance, to guess which identified site is correct. Additionally, even after companies resolved the misspellings and/or inaccuracies, Authorized Users have had to manually reassign all sites, facilities, and Authorized Users to the account before reporting could begin. In some instances, the names of parent companies were inaccurate and other errors were identified with Dunn & Bradstreet identifiers. This process was made even more complicated with the new methods for completing co-manufacturing submissions because the facility ID for the Contracting Company and the Producing Company must match before the submission process can begin.

Inexact entries: The system requires "exact matching" of chemical entries by CASRN; any single mismatch by hyphen, hidden or special characters, or spacing results in a validation error. Of concern is that submitters cannot tell why they are receiving validation errors, as further noted below.

General form completion issues:

- Inability to Enter/Align Data – Reporters have been unable to enter: a Zero (-0-) for Physical Form value of a gas/vapor or Industrial Process and Use information; information related to Significant New Use Rule chemicals; or align the new OECD Codes with the former use codes. In addition, the cells within the Form U often would not accept and/or recognize data entered and created validation errors. On most occasions, Reporters had to wait weeks-to-months for these issues to be resolved.
- Miscellaneous Validation Errors – Validation warnings often did not link clearly to the specific chemical triggering the warning message, creating tedious and burdensome re-review of information to isolate and correct the entry. Later in the process, hidden characters, blank spaces, and special characters occurred relating to errors. The feature is not intuitive or apparent, nor is it clear from instructions, and has resulted in time lost either seeking EPA help desk assistance or troubleshooting.

* * * * * *

ACC strongly urges EPA to extend the deadline to complete CDR submissions by 60 days, based on the cumulative impact of the technical issues noted above. Should this request be granted, ACC requests that notice be provided directly to the regulated industry prior to its appearance in the Federal Register to preempt any delay in the official announcement.

If we can provide any additional information on ACC's concerns, please contact me (202 249 6400; mike_walls@americanchemistry.com) or Kat Gale (202 249 6129; Kat_Gale@americanchemistry.com).

Sincerely,

Michael P. Walls
Vice President
Regulatory & Technical Affairs

cc: Alex Dunn
David Widawsky
David Turk